

efficiency for broiler chickens and growing turkeys.

(2) *Swine*—(i) *Amount per ton*. Oleandomycin, 5 to 11.25 grams.

(ii) *Indications for use*. For increased rate of weight gain and improved feed efficiency in growing-finishing swine.

[40 FR 13959, Mar. 27, 1975, as amended at 44 FR 40283, July 10, 1979; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987]

§ 558.450 Oxytetracycline.

(a) *Approvals*. Type A medicated articles:

(1) 10, 20, 30, 50, 100, and 200 grams per pound to 000069 in § 510.600(c) of this chapter.

(2) 50 and 100 grams per pound to 053389 in § 510.600(c) of this chapter.

(b) *Special considerations*. (1) In accordance with § 558.5 labeling shall bear the statement: "FOR USE IN DRY

ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

(2) The articles in paragraph (a)(1) of this section contain an amount of mono-alkyl (C₈-C₁₈) trimethylammonium oxytetracycline expressed in terms of an equivalent amount of oxytetracycline hydrochloride or an amount of oxytetracycline dihydrate base expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(3) The articles in paragraph (a)(2) of this section contain an amount of mono-alkyl (C₈-C₁₈) trimethylammonium oxytetracycline expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(c) *Related tolerances*. See § 556.500 of this chapter.

(d)(1) *Conditions of use*. It is used in feed as follows:

TABLE 1

Oxytetracycline amount	Combination	Indications for use	Limitations	Sponsor
(i) 10 to 20 grams per ton (g/ton)		Sheep; increased rate of weight gain and improved feed efficiency.	000069, 053389
(ii) 10 to 50 g/ton		1. Chickens; increased rate of weight gain and improved feed efficiency.	Do not feed to chickens producing eggs for human consumption.	Do.
		2. Growing turkeys; increased rate of weight and improved feed efficiency.	Do not feed to turkeys producing eggs for human consumption.	Do.
		3. Swine; increased rate of weight and improved feed efficiency.	Do.
(iii) 100 g/ton		Turkeys; control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 days (d); do not feed to turkeys producing eggs for human consumption.	Do.
(iv) 100 to 200 g/ton		Chickens; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> ; control of fowl cholera caused by <i>Pasteurella multocida</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feed, withdraw 3 d before slaughter.	Do.
	Nequinat 18.16 g/ton (0.002%)	Chickens; control of infectious synovitis caused by <i>M. synoviae</i> ; control of fowl cholera caused by <i>P. multocida</i> susceptible to oxytetracycline; as an aid in the control of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i>do	000069

TABLE 1—Continued

Oxytetracycline amount	Combination	Indications for use	Limitations	Sponsor
(v) 200 g/ton		Turkeys; control of infectious synovitis caused by <i>M. synoviae</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.	000069, 053389
(vi) 400 g/ton	Monensin 90 to 110 g/ton	Chickens; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>Escherichia coli</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter.	Do.
		Chickens; control of CRD and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to oxytetracycline; and as an aid in the prevention of coccidiosis caused by <i>E. necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i>do	000069
	Nequinatate 18.16 g/ton (0.002%)	Chickens; control of CRD and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to oxytetracycline; as an aid in prevention of coccidiosis caused by <i>E. tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i>do	Do.
(vii) 500 g/ton	Monensin 90 to 110 g/ton	Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by <i>E. coli</i> susceptible to oxytetracycline.	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter.	000069, 053389
		Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by <i>E. coli</i> susceptible to oxytetracycline; as an aid in the prevention of coccidiosis caused by <i>E. necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i>do	000069
	Salinomycin 40 to 60 g/ton	Chickens; reduction of mortality due to air sacculitis (air-sac-infection) caused by <i>E. coli</i> susceptible to oxytetracycline; prevention of coccidiosis caused by <i>E. necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i>do	000069, 012799

TABLE 1—Continued

Oxytetracycline amount	Combination	Indications for use	Limitations	Sponsor
(viii) 0.05 to 0.1 milligram/pound (mg/lb) of body weight daily.		Calves (up to 250 lb); for increased rate of weight gain and improved feed efficiency.	Feed continuously; in milk replacers or starter feed.	000069, 053389
(ix) 10 mg/lb of body weight daily.		1. Calves and beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia (shipping fever complex) caused by <i>P. multocida</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; in feed or milk replacers; withdraw 5 d before slaughter.	Do.
		2. Calves (up to 250 lb); treatment of bacterial enteritis caused by <i>E. coli</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; in milk replacers or starter feed; withdraw 5 d before slaughter.	Do.
		3. Sheep; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.	Do.
		4. Swine; treatment of bacterial enteritis caused by <i>E. coli</i> and <i>Salmonella choleraesuis</i> susceptible to oxytetracycline and treatment of bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.	Do.
		5. Breeding swine; control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to oxytetracycline.	Feed continuously for not more than 14 d; withdraw 5 d before slaughter.	Do.
(x) 25 mg/lb of body weight		Turkeys; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.	Do.
(xi) 25 mg/head/day		Calves (250 to 400 lb); increased rate of weight gain and improved feed efficiency.	Do.
(xii) 75 mg/head/day		Growing cattle (over 400 lb); increased rate of weight gain; improved feed efficiency, and reduction of liver condemnation due to liver abscesses.	Do.
(xiii) 0.5 to 2.0 g/head/day		Cattle; prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 d before and after arrival in feedlots.	Do.

TABLE 1—Continued

Oxytetracycline amount	Combination	Indications for use	Limitations	Sponsor
(xiv) 200 mg/colony		Honey bees; control of American foulbrood caused by <i>Bacillus larvae</i> and European foulbrood caused by <i>Streptococcus pluton</i> susceptible to oxytetracycline.	Remove at least 6 weeks prior to main honey flow.	Do.

(2) It is used in fish feed as follows:

TABLE 2

Oxytetracycline amount	Combination	Indications for use	Limitations	Sponsor
(i) 250 mg/kilogram of fish/d (11.35 g/100 lb of fish/d).		Pacific salmon for marking of skeletal tissue.	For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days in feed containing oxytetracycline hydrochloride or mono-alkyl (C ₈ –C ₁₈) trimethyl ammonium oxytetracycline; fish not to be liberated for at least 7 d following the last administration of medicated feed.	000069
(ii) 2.5 to 3.75 g/100 lb of fish/d.		1. Salmonids; control of ulcer disease caused by <i>Hemophilus piscium</i> , furunculosis caused by <i>Aeromonas salmonicida</i> , bacterial hemorrhagic septicemia caused by <i>A. liquefaciens</i> , and pseudomonas disease.	Administer as mono-alkyl (C ₈ –C ₁₈) trimethyl ammonium oxytetracycline in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 9 ±C (48.2 ±F).	000069
		2. Catfish; control of bacterial hemorrhagic septicemia caused by <i>A. liquefaciens</i> and pseudomonas disease.	Administer as mono-alkyl (C ₈ –C ₁₈) trimethyl ammonium oxytetracycline in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 16.7 ±C (62 ±F).	000069
(iii) 1 g/lb of medicated feed.		Lobsters; control of gaffkemia caused by <i>Aerococcus viridans</i> .	Administer as sole ration for 5 consecutive days in feed containing monoalkyl (C ₈ –C ₁₈) trimethyl ammonium oxytetracycline; withdraw medicated feed 30 d before harvesting lobsters.	000069

(3) Oxytetracycline may be used in accordance with the provisions of this section in the combinations provided as follows:

- (i) Robenidine hydrochloride in accordance with § 558.515.
(ii) Lasalocid as in § 558.311.

Food and Drug Administration, HHS

§ 558.465

(iii) Melengestrol acetate as in § 558.342.

[61 FR 51590, Oct. 3, 1996, as amended at 63 FR 41192, Aug. 3, 1998]

§ 558.460 Penicillin.

(a) *Specifications.* As penicillin procaine G or feed grade penicillin procaine.

(b) *Sponsors.* Type A medicated articles: To 000069, 100 grams per pound. To 046573, 100 and 227 grams per pound.

(c) Related tolerances. See § 556.510 of this chapter.

(d) *Conditions of use.* (1) It is used as follows:

Penicillin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 2.4 to 50	Chickens, turkeys, and pheasants; for increased rate of weight gain and improved feed efficiency..	Do not feed to poultry producing eggs for human consumption..	000069, 046573.
(ii) 5 to 20	Quail; for increased rate of weight gain and improved feed efficiency..	Quail; not over 5 weeks of age.	Do.
(iii) 10 to 50	Swine; for increased rate of weight gain and improved feed efficiency..	Do.

(2) Penicillin may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium plus ethopabate in accordance with § 558.58.

(iii)-(v) [Reserved]

(vi) Hygromycin B in accordance with § 558.274.

(vii) Roxarsone and zoalene in accordance with § 558.680.

(viii) Zolene in accordance with § 558.680.

[41 FR 11004, Mar. 15, 1976, as amended at 42 FR 18618, Apr. 8, 1977; 42 FR 36995, July 19, 1977; 47 FR 42103, Sept. 24, 1982; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 58 FR 30120, May 26, 1993; 60 FR 39847, Aug. 4, 1995; 63 FR 36179, July 2, 1998]

§ 558.464 Poloxalene.

(a) *Approvals.* (1) Dry Type A medicated articles: 53 percent to 000069 in § 510.600(c) of this chapter.

(2) Liquid Type A medicated articles: 99.5 percent to 000069 in § 510.600(c) of this chapter.

(b) *Conditions of use.* (1) For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle.

(2) Poloxalene dry Type A article and liquid Type A article must be thoroughly blended and evenly distributed in feed prior to use. This may be accomplished by adding the Type A arti-

cle to a small quantity of feed, mixing thoroughly, then adding this mixture to the remaining feed and again mixing thoroughly. Dosage is 1 gram of poloxalene per 100 pounds of body weight daily and continued during exposure to bloat producing conditions. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat dosage if animals are exposed to bloat-producing conditions more than 12 hours after the last treatment. Do not exceed the higher dosage levels in any 24-hour period.

[40 FR 39857, Aug. 29, 1975, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 56 FR 50654, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995]

§ 558.465 Poloxalene free-choice liquid Type C feed.

(a) *Approvals.* Type A medicated articles: 99.5 percent to 000069 in § 510.600(c) of this chapter.

(b) *Conditions of use.* (1) For control of legume (alfalfa, clover) and wheat pasture bloat in cattle, use 7.5 grams of poloxalene per pound of liquid Type C feed (1.65 percent weight/weight). Each animal must consume 0.2 pound of Type C feed per 100 pounds of body weight daily for adequate protection.

(2) For control of legume (alfalfa, clover) bloat in cattle grazing of prebloom legumes, use 10.00 grams of poloxalene